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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,692	10/05/2006	Prediman K. Shah	67789-101US0	2885

50670 7590 03/24/2010  
DAVIS WRIGHT TREMAINE LLP/Los Angeles  
865 FIGUEROA STREET  
SUITE 2400  
LOS ANGELES, CA 90017-2566

EXAMINER
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EPPS -SMITH, JANET L

ART UNIT	PAPER NUMBER
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1633

NOTIFICATION DATE	DELIVERY MODE
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03/24/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentlax@dwt.com  
sethlevy@dwt.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/599,692	<b>Applicant(s)</b> SHAH ET AL.	
	<b>Examiner</b> Janet L. Epps-Smith	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/19/2010</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-16 and 29-35 withdrawn as being directed to a non-elected invention are now cancelled by Applicants.
2. Claims 17-28 are now pending for examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 103***

4. Claims 17-28 remain rejected under 35 U.S.C. 103(a) as being obvious over Fan et al. in view of Oka et al. and Sharif et al.
5. Applicant's arguments filed 01/19/2010 have been fully considered but they are not persuasive. In response to the Oka et al. reference, Applicants assert that because the reference was published less than a year before the priority date of the present application and describes the work of inventors. In addition, Applicants have submitted a Declaration under 37 CFR 1.131 by Dr. Shah to overcome this reference. According to Dr. Shah, the conception of the invention as claimed was completed prior to the publication of the Oka et al. reference. The Declaration under 37 CFR 1.131 filed by Prediman K. Shah has been considered but is ineffective to overcome the Oka et al. reference. In the instant case, the Declaration under 37 CFR 1.131 was signed only by Dr. Prediman, and did not include the signatures of the Saswati Chatterjee and Kamehameha Wong. As per MPEP § 715 [R-3](a) "[W]hen any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the

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rejected claim, the owner of the patent under reexamination, or the party qualified under §§ 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based.” According to this passage of the MPEP “the inventor of the subject matter of the rejected claim,” may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim. According to the Declaration of Inventorship filed 10/05/2006, the inventors of the claimed invention include Saswati Chatterjee and Kamehameha Wong, In addition to Prediman Shah.

6. Moreover, Dr. Shah submitted a Declaration under 37 CFR 1.132, wherein Dr. Shah stated that the Patel et al. reference describes solely the work of Applicants in the instant application. However, contrary to Applicant’s assertions, the Patel et al. reference was not applied in the instant rejection under 35 USC 103(a).

Applicants have not provided any arguments to overcome the teachings set forth in the Fan et al. or Sharifi et al. reference. Therefore, even if the Oka et al. reference was overcome, it remains that Fan et al. teach the AAV-based delivery of human apolipoprotein A-I into the skeletal muscle for the treatment of atherosclerosis, and Sharif et al. teach adeno-associated virus mediated Apo A-I Milano gene therapy for the treatment of atherosclerosis and restenosis. Sharif et al. provided preliminary data using in vivo studies demonstrating successful gene transcription in vivo. In order to increase production of Apo A-I Milano, the AAV vector was optimized. The claimed invention would remain obvious over Fan et al. in view of Sharifi et al. However, since

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Applicants have not overcome the Oka et al. reference, it remains that it would have been obvious to the ordinary skilled artisan to modify the teachings of Fan et al., Oka et al. and Sharif et al. in the design of the claimed invention. First, one of ordinary skill in the art would have been motivated to modify the teachings of Fan et al. with the teachings of Oka et al. and Sharif et al. since Oka et al. in particular, teach that Apo-A-I Milano was demonstrated to have a greater anti-atherogenic effect than that observed for wild-type Apo A-I.

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/  
Primary Examiner, Art Unit 1633